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10/057,323	01/25/2002	Harry R. Davis	CV01489K	1525

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/057,323
Filing Date: January 25, 2002
Appellant(s): DAVIS ET AL.

Bryan P. Clark
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For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 16, 2009 appealing from the Office action mailed September 26, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,846,966	ROSENBLUM et al.	12-1998
EP 0 457 514	BERGEY et al.	11-1991

The Medical Letter on Drugs and Therapeutics, 1998, 40(1030): 68-69

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32, 102-104, 106-108, 110-112, and 126 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenblum et al. (US Patent 5,846,966), Medical Letter (The Medical Letter on Drugs and Therapeutics, 1998, 40;1030:68-69), references of record, and EP 0 457 514 ('514).

Rosenblum et al. also teaches the elected compound herein, ezetimibe, useful for reducing cholesterol and the risk of artherosclerosis (See the abstract, also col. 32, Example 6, Compound 6A, and col. 40, line 52 particularly).

Medical Letter teaches fenofibrate as useful in reducing serum cholesterol level (See page 68 – 69).

'514 teaches captopril significantly reduce serum cholesterol in hypercholesterolemic patients and being beneficial as anti-atherosclerotic agents to slow or regress the progress of atherosclerosis (See page 2, lines 17-20, 30-40 for example). '514 also teaches the combination of captopril with an additional cholesterol lowering agent such as HMG-CoA reductase inhibitors (See the abstract and claims 1-3 for example).

The references do not expressly teach a composition containing fenofibrate and ezetimibe, and captopril together.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate ezetimibe, fenofibrate, and captopril together in a single composition.

One of ordinary skill in the art would have been motivated to incorporate both ezetimibe, fenofibrate, and captopril together in a single composition. The prior art teaches that ezetimibe, fenofibrate, and captopril as useful in reducing cholesterol and reduce the risk of atherosclerosis individually. Therefore, combining two or more agents, which are known to be useful to reduce cholesterol and reduce the risk of atherosclerosis individually, into a single composition useful for the very same purpose is *prima facie* obvious (See *In re Kerkhoven* 205 USPQ 1069). Furthermore, the examiner notes that captopril is known to be useful in combination with cholesterol lowering agents as disclosed in '514. Therefore, possessing the teachings of the cited prior art, one of ordinary skill in the art would have been motivated to incorporate the herein claimed actives together in a single composition for reducing cholesterol and the risk of atherosclerosis.

(10) Response to Argument

Appellant's arguments in the Brief filed December 2, 2008 averring the cited prior art's failure to provide motivation or suggestion to combine the herein claimed actives into a single composition, are not convincing. The examiner notes that the basis of the rejection resides on the fact that the herein claimed actives are all well-known individually to be useful in reducing cholesterol and the risk of atherosclerosis. Therefore, it flows logically to combine these agents into a single composition useful for the very same purpose, absent evidence to the contrary (See *Kerkhoven* supra). Therefore, even though the mechanism of ezetimibe may not be fully understood at the time of filing, it is known to be useful in reducing cholesterol; therefore, combining the

herein claimed actives, which all three of the compounds are known in reducing the risk of atherosclerosis individually, into a single composition would be obvious as discussed above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/San-ming Hui/

Primary Examiner, Art Unit 1617

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/Johann R. Richter/

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